

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

LOUIS J. PAWLOWSKI, DNP,

Plaintiff,

v.

21-CV-931-LJV
DECISION & ORDER

XAVIER BECERRA, *Secretary of the
United States Department of Health and
Human Services, et al.*,

Defendants.

On August 16, 2021, the plaintiff, Louis J. Pawlowski, DNP, filed this action.

Docket Item 1. He alleged that the defendants, United States Department of Health and Human Services (“HHS”) Secretary Xavier Becerra and National Government Services, Inc. (“NGS”) (collectively, “the government”), violated his due process rights when they notified him that his Medicare enrollment would be revoked on August 22, 2021. *Id.* That same day, Dr. Pawlowski also moved for a temporary restraining order and a preliminary injunction.¹ Docket Item 3.

Soon after, the parties stipulated that any revocation of Dr. Pawlowski’s Medicare enrollment and billing privileges and any resulting inclusion on the Centers for Medicare and Medicaid Services (“CMS”) preclusion list would not become effective until twenty-one days after CMS decided Dr. Pawlowski’s request for reconsideration of that decision. Docket Item 15. The government then moved to dismiss on September 16,

¹ Dr. Pawlowski initially sought temporary relief to stay the effective date of the revocation until he completed the administrative appeals process and his claims were adjudicated in this Court. See Docket Item 7.

2021. Docket Item 23. After Dr. Pawlowski filed an amended complaint, Docket Item 27, the government renewed its motion to dismiss on October 21, 2021, Docket Item 31. Dr. Pawlowski responded on November 8, 2021, Docket Item 37, and the government replied on November 15, 2021, Docket Item 38. This Court held oral argument on the government's motion on November 19, 2021, Docket Item 39, and the parties then submitted additional briefing, see Docket Items 41, 43.

In the meantime, on October 15, 2021, Dr. Pawlowski asked CMS to reconsider the revocation and preclusion decisions. See Docket Item 38-2. On January 28, 2022, CMS notified Dr. Pawlowski that it upheld the initial determination to revoke his Medicare enrollment, bar him from re-enrollment for ten years, and place him on the CMS preclusion list. Docket Item 44. After an additional extension of time, the effective date of the revocation of Dr. Pawlowski's enrollment and his placement on the preclusion list was extended until March 4, 2022. Docket Item 46.

For the following reasons, the government's motion to dismiss is granted, and Dr. Pawlowski's motion for a preliminary injunction therefore is denied as moot.

FACTUAL BACKGROUND

Dr. Pawlowski is a "nurse practitioner who holds a Doctorate in Nursing Practice" and "specializes in pain management." Docket Item 27 at ¶ 11. He "has a private practice with a principal place of business in Orchard Park, New York." *Id.* "Since 2004[,] he has been enrolled with CMS to be reimbursed for services provided to Medicare beneficiaries." *Id.* Medicare reimbursement makes up about half the revenue of Dr. Pawlowski's practice. *Id.* at ¶ 20.

On October 2, 2020, Qlarant, an “Investigations Medicare Drug Integrity Contractor” that contracts with CMS to “conduct program-integrity functions,” sent Dr. Pawlowski a letter “infor[ming] [him] that Qlarant[] . . . [would] be conducting a review of medical and/or prescription records for [his] patients.” Docket Item 31-4 at 2. Qlarant requested medical records associated with certain beneficiaries, including information related to opioid prescriptions. *Id.* at 2-3. Although any response from Dr. Pawlowski was “voluntary,” Qlarant informed him that it was “required to notify CMS” if he failed to supply the requested records. *Id.* at 3. Dr. Pawlowski responded with the requested records on October 29, 2020. See Docket Item 31-5.

Nearly nine months passed before Dr. Pawlowski received a letter from NGS, the Medicare Administrative Contractor that covers New York, notifying him that his Medicare enrollment and “privileges [would be] revoked effective August 22, 2021.” Docket Item 27-1 at 2; Docket Item 27 at ¶¶ 13, 26. That letter informed Dr. Pawlowski that CMS had “determined that [he] ha[d] engaged in a pattern or practice of prescribing Part D drugs that represents a threat to the health and safety of Medicare beneficiaries” in violation of 42 C.F.R. § 424.535(a)(14)(i). See Docket Item 27-1 at 2; Docket Item 27 at ¶ 26. That regulation provides that a supplier’s Medicare enrollment may be revoked if “CMS determines that the physician or eligible professional has a pattern or practice of prescribing Part B or D drugs that . . . is abusive or represents a threat to the health and safety of Medicare beneficiaries or both.” 42 C.F.R. § 424.535(a)(14)(i). “In making [that] determination,” CMS considers, among other factors, “[w]hether the physician or eligible professional has prescribed controlled substances in excessive dosages that

are linked to patient overdoses," *id.* § 424.535(a)(14)(i)(C), as well as "[a]ny other relevant information provided to CMS," *id.* § 424.535(a)(14)(i)(H).

The July 23 letter invoked those factors as bases for the revocation. First, the letter noted that Dr. Pawlowski had "prescribed excessive dosages of opioids that [were] linked to three [] patient overdoses[]" for two "unique beneficiaries," in "violation of [42 C.F.R. §] 424.535(a)(14)(i)(C)." Docket Item 27-1 at 2. The letter also noted "inappropriate prescribing behavior" and "high-opioid dosages [that] were not supported by the records and documentation," both in violation of 42 C.F.R. § 424.535(a)(14)(i)(H). *Id.* The letter informed Dr. Pawlowski that as a result of the revocation of his Medicare enrollment, he also would be placed on the CMS preclusion list and would be barred from submitting an application to re-enroll for ten years. *Id.* at 3, 5.

The letter notified Dr. Pawlowski that he had the "right to submit [a] reconsideration request," which would result in "an independent review conducted by a person not involved in the initial determination." *Id.* at 3 (capitalization removed). But because the revocation was set to go into effect on August 22, 2021, any decision on Dr. Pawlowski's reconsideration request would almost certainly come after his privileges had been revoked. *Id.* at 2. So Dr. Pawlowski sought immediate relief in this Court to stay the effective date of the revocation, see Docket Item 3, after which the government stipulated that the effective date of any revocation and inclusion on the preclusion list would be stayed until twenty-one days after a decision on Dr. Pawlowski's reconsideration request, see Docket Item 15.

On September 7, 2021, Dr. Pawlowski requested additional documents related to the July 23 letter, including medical records associated with the initial revocation

decision. See Docket Item 31-2 at ¶ 9; Docket Item 31-6. On October 15, 2021, he submitted his request for reconsideration. See Docket Item 31-2 at ¶ 14; Docket Item 38-2. That request ran over 300 pages and attached fifteen exhibits, which included “supplemental medical records” for nine patients as well as affidavits from three physicians and a medical billing expert. See Docket Item 38-1 at ¶ 4; Docket Item 38-2. CMS denied Dr. Pawlowski’s request for reconsideration on January 28, 2022. Docket Item 44. More specifically, CMS concluded that “Dr. Pawlowski engaged in a pattern or practice of prescribing drugs [that] is abusive and/or represents a threat to the health and safety of Medicare beneficiaries” and consequently “uph[eld] the revocation of Dr. Pawlowski’s Medicare enrollment pursuant to [42 C.F.R.] § 424.535(a)(14).” *Id.* at 19. Likewise, CMS upheld the decision to include Dr. Pawlowski on the CMS preclusion list and to impose a ten-year re-enrollment bar beginning on the date that Dr. Pawlowski’s enrollment was revoked. *Id.* at 19-21.

Dr. Pawlowski challenges that entire process. See Docket Item 27. More specifically, he alleges that the defendants “fail[ed] to afford him any opportunity to be heard prior to the revocation determination” and did “not provid[e] him an opportunity to rebut findings that influenced the revocation determination.” *Id.* at 11-12 (capitalization removed). Dr. Pawlowski also challenges the defendants’ application and interpretation of 42 C.F.R. § 424.535(a)(14)(i), certain statements in an introductory section of CMS’s program manual, and the decision to impose a ten-year re-enrollment bar. See *id.* at ¶¶ 36-52, 57-61. Finally, Dr. Pawlowski argues that NGS, not CMS, improperly made the initial revocation decision, and he maintains that the HHS Secretary had “no statutory authority to terminate” his enrollment. *Id.* at ¶¶ 53-56, 62-64 (capitalization removed).

LEGAL PRINCIPLES

I. SUBJECT MATTER JURISDICTION

A court “properly dismisses an action under [Federal Rule of Civil Procedure] 12(b)(1) for lack of subject matter jurisdiction if the court ‘lacks the statutory or constitutional power to adjudicate it.’” *Cortlandt St. Recovery Corp. v. Hellas Telecomm., S.à.r.l.*, 790 F.3d 411, 416-17 (2d Cir. 2015) (quoting *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000)). “When considering a motion to dismiss for lack of subject matter jurisdiction[,] a court must accept as true all material factual allegations in the complaint.” *Jiles v. Rochester Genesee Reg’l Transp. Auth.*, 317 F. Supp. 3d 695, 699 (W.D.N.Y. 2018) (quoting *Shipping Fin. Servs. Corp. v. Drakos*, 140 F.3d 129, 131 (2d Cir. 1998)). On a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1), a court “may consider affidavits and other materials beyond the pleadings to resolve the jurisdictional issue.” *J.S. ex rel. N.S. v. Attica Cent. Sch.*, 386 F.3d 107, 110 (2d Cir. 2004).

II. FAILURE TO STATE A CLAIM

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at 556). In deciding a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court “accept[s] all factual allegations as true and draw[s] all reasonable inferences in favor of the plaintiff.” *Trs. of*

Upstate N.Y. Eng'r's Pension Fund v. Ivy Asset Mgmt., 843 F.3d 561, 566 (2d Cir. 2016).

DISCUSSION

I. JURISDICTION

Because “[s]ubject matter jurisdiction is a threshold question that must be resolved before proceeding to the merits,” see *United States v. Bond*, 762 F.3d 255, 263 (2d Cir. 2014) (alterations, citation, and internal quotation marks omitted), this Court first addresses whether it has jurisdiction to hear Dr. Pawlowski’s claims. The government contends that the Court does not, citing the Medicare Act’s strict claim-channeling and jurisdiction-stripping provisions that require exhaustion prior to judicial review.² See Docket Item 31-1 at 10-24.

“The Medicare Act incorporates claim-channeling and jurisdiction-stripping provisions from the Social Security Act.” *Avon Nursing & Rehab. v. Becerra*, 995 F.3d 305, 309 (2d Cir. 2021). Section 405(g) of the Social Security Act, the “claim-channeling” provision, provides that “a party, ‘after any final decision of the Secretary made after a hearing, may obtain a review of such decision in federal district court.’” *Id.* (alterations omitted) (quoting 42 U.S.C. § 405(g)). And the “jurisdiction-stripping” provision, section 405(h), provides that:

The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the

² The jurisdictional analysis applies to NGS as well as HHS. See *S. Rehab. Grp., P.L.L.C. v. Sec'y of Health & Human Servs.*, 732 F.3d 670, 680 n.7 (6th Cir. 2013) (noting that section 405(h) applies to “the Secretary’s contractors”).

United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

See 42 U.S.C. § 405(h); *id.* § 1395ii (applying section 405(h) to the Medicare Act).

The judicial review “bar of [section] 405(h) reaches beyond ordinary administrative law principles of ‘ripeness’ and ‘exhaustion of administrative remedies.’” *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12 (2000) (citation omitted). Indeed, section 405(h) provides that where a claim arises under the Medicare Act—that is, “where ‘both the standing and the substantive basis for the presentation’ of a claim is the Medicare Act”—that claim “must be ‘channeled’ through the administrative process” before obtaining review in federal court. *Id.* at 12 (quoting *Heckler v. Ringer*, 466 U.S. 602, 614-15 (1984)). And that channeling requirement “applies to ‘virtually all legal attacks,’ whether procedural or substantive, constitutional or non-constitutional, future or present, legal or fact-specific.” *Arriva Med. LLC v. U.S. Dep’t of Health & Human Servs.*, 239 F. Supp. 3d 266, 278 (D.D.C. 2017) (quoting *Ill. Council*, 529 U.S. at 13-14).

Dr. Pawlowski’s claims plainly arise under the Medicare Act; he makes no effort to argue otherwise. See, e.g., Docket Item 27 at ¶ 14 (“This action arises under . . . the Medicare Act”). So his claims are subject to the claim-channeling and exhaustion requirements prior to judicial review. Nevertheless, Dr. Pawlowski contends that he is not required to exhaust the administrative process before pursuing judicial review based on two exceptions to the exhaustion requirement. First, Dr. Pawlowski argues that requiring exhaustion now would foreclose any future review of his claims. Second, Dr. Pawlowski argues that even if a court could eventually review his claims and exhaustion

therefore cannot be excused on the first ground, this Court nevertheless should deem the exhaustion requirement waived under the circumstances here.

A. The *Michigan Academy* Exception

Dr. Pawlowski's first argument is that the claim-channeling and exhaustion requirements of the Medicare Act do not apply because requiring exhaustion now would "leave [him] without any statutory basis for judicial review of [the] agency action." Docket Item 37 at 5 (citing *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667 (1986)). Under the so-called *Michigan Academy* exception, proceeding through the administrative process is not required "where [the] application of [section] 405(h) would not simply channel review through the agency, but would mean no review at all." *III. Council*, 529 U.S. at 19. So the Court first considers whether requiring Dr. Pawlowski to first proceed through the administrative process would be tantamount to forever foreclosing judicial review—in other words, whether the channeling requirement does not apply because if it did, this Court could *never* consider Dr. Pawlowski's claims.

The precise provision that might permit a court to review Dr. Pawlowski's claims has been the source of some dispute in this case. See, e.g., Docket Item 41 at 2-5 (supplemental briefing from Dr. Pawlowski contending that no court could review his claims); Docket Item 43 at 3-6 (same from the government arguing the opposite). The government relies on 42 U.S.C. § 1395cc(j)(8), which provides that a "provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) . . . is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A)." Docket Item 43 at 4-5 (alterations omitted) (quoting 42 U.S.C. § 1395cc(j)(8)); see also 42 U.S.C. § 1395cc(h)(1)(A)

(providing that a party is entitled to “judicial review of the Secretary’s final decision . . . as is provided in section 405(g)”). Dr. Pawlowski contends that section 1395cc(j)(8) does not provide judicial review under section 405(g) for his claims, which hinge on the revocation of billing privileges rather than the “denial of an application for Medicare enrollment or re-enrollment.” Docket Item 41 at 4.

Admittedly, section 1395cc(j)(8) does not explicitly address the revocation of billing privileges. But relevant regulations have interpreted that provision as providing judicial review in precisely those circumstances. See 42 C.F.R. § 498.1(g) (“Section 1866(j) . . . provides for a hearing and judicial review for any provider or supplier . . . whose billing privileges are revoked.”). And courts have reviewed claims challenging the revocation of a provider’s or supplier’s billing privileges—that is, the very claims that Dr. Pawlowski contends could never be reviewed in court—under section 405(g). See, e.g., *Lilia Gorovits, M.D., P.C. v. Becerra*, 2021 WL 1962903, at *3 (E.D. Pa. May 17, 2021) (“A Medicare provider whose billing privileges are revoked is entitled to judicial review of the decision of revocation.” (citing 42 U.S.C. § 1395cc(j)(8)); *Foo v. Azar*, 420 F. Supp. 3d 1100, 1105 (D. Haw. 2019) (reviewing supplier’s challenge to revocation of Medicare enrollment and billing privileges “brought pursuant to 42 U.S.C. § 405(g)”; *Fayad v. Sebelius*, 803 F. Supp. 2d 699, 702 (E.D. Mich. 2011) (same). So Dr. Pawlowski’s contention that no court could ever review his claims if he had to exhaust his administrative remedies beforehand is belied by decisions of other federal courts doing just that.

Dr. Pawlowski could eventually return to court after proceeding through the administrative process.³ Because that means Dr. Pawlowski could seek judicial review at a later time, he is not excused from exhaustion based on *Michigan Academy*.

B. Waiver of Exhaustion

Dr. Pawlowski next argues that even if his claims must first be channeled through the administrative process prior to obtaining judicial review—which, for all the reasons above, they must be—this Court nevertheless should waive exhaustion here.⁴ “The factors courts have cited to excuse failure to exhaust are: (1) that the claim is collateral to a demand for benefits; (2) that exhaustion would be futile; and (3) that plaintiffs would suffer irreparable harm if required to exhaust administrative remedies.”⁵ *Pavano v. Shalala*, 95 F.3d 147, 150 (2d Cir. 1996). “Exhaustion is the rule, waiver the exception.”⁶ *Abbey v. Sullivan*, 978 F.2d 37, 44 (2d Cir. 1992).

³ Indeed, the case that Dr. Pawlowski points to as presenting “circumstances similar to those here,” *see* Docket Item 37 at 35, contemplates that judicial review is available only after administrative exhaustion. *See Robie v. Price*, 2017 WL 3097529, at *2 (S.D.W. Va. July 20, 2017) (“Federal courts are barred from reviewing claims [challenging] the revocation of a physician’s Medicare billing privileges[] unless there has been a final decision by the Secretary.” (citing 42 U.S.C. §§ 405(g), (h)).

⁴ As can be gleaned from the quotations in this paragraph and below, courts use the terms “waive” and “excuse” interchangeably in this context.

⁵ Some courts have evaluated whether a plaintiff has made a colorable showing of irreparable harm in conjunction with collaterality when evaluating whether exhaustion should be excused. *See, e.g., Blossom South, LLC v. Sebelius*, 987 F. Supp. 2d 289, 296-97 (W.D.N.Y. 2013). Because Dr. Pawlowski’s claims are not collateral for all the reasons stated below, a colorable showing of irreparable harm under that framework does not excuse exhaustion here.

⁶ Waiver of exhaustion also requires a “nonwaivable . . . requirement that a claim” be “presented to the Secretary.” *See Mathews v. Eldridge*, 424 U.S. 319, 328 (1976). The parties do not dispute that Dr. Pawlowski has satisfied that requirement.

1. Whether Dr. Pawlowski's Claims Are Wholly Collateral

For a claim to be “wholly collateral,” it cannot be the “vehicle by which [the plaintiff] seek[s] to reverse” the agency’s decision. See *Elgin v. Dep’t of Treasury*, 567 U.S. 1, 22 (2012). “If the court must examine the merits of the underlying dispute, delve into the statute and regulations, or make independent judgments as to [the plaintiff’s] eligibility under a statute, the claim is not collateral.” *Fam. Rehab., Inc. v. Azar*, 886 F.3d 496, 503 (5th Cir. 2018). “And if [the plaintiff] request[s] relief that is proper under the organic statute—by requesting that benefits or a provider status be *permanently* reinstated—the claim is not collateral.” *Id.* (emphasis in original). Nor can a party “avoid the Medicare Act’s administrative procedures for reviewing the Secretary’s determinations simply by making purely legal constitutional or statutory arguments.” *Cathedral Rock of N. Coll. Hill, Inc. v. Shalala*, 223 F.3d 354, 363 (6th Cir. 2000). “Rather, a court must examine whether the allegedly collateral claim involves completely separate issues from the party’s claim that it is entitled to benefits or continued participation in the Medicare program or whether it is inextricably intertwined with its substantive claim to benefits or participation.” *Id.*

Most of the alleged due process violations outlined in Dr. Pawlowski’s amended complaint are, at bottom, “inextricably intertwined” with his claim for continued participation in the Medicare program. For example, Dr. Pawlowski challenges the government’s determination that he had a “pattern or practice” of issuing improper prescriptions, see 42 C.F.R. § 424.535(a)(14); the government’s failure to adequately evaluate various regulatory considerations for revocation under 42 C.F.R. § 424.535(a)(14)(i); the language in a CMS manual; the “conflicting standards” about which entity (NGS or CMS) can and should make revocation determinations; the

government's application of the re-enrollment bar regulation in 42 C.F.R. § 424.535(c); and the Secretary's statutory authority to revoke Dr. Pawlowski's enrollment on the grounds relied on. See Docket Item 27 at ¶¶ 36-64 (capitalization removed).

But evaluating those challenges would require this Court to "examine the merits of the underlying dispute, delve into the statute and regulations, [and] make independent judgments as to [Dr. Pawlowski's] eligibility" under the statutory scheme. *See Fam. Rehab.*, 886 F.3d at 503. Indeed, Dr. Pawlowski advanced some of the very same claims he presses in this Court as part of his reconsideration request to CMS. Compare, e.g., Docket Item 27 at ¶¶ 36-49 (contending that the defendants improperly interpreted the regulatory criteria of 42 C.F.R. § 424.535(a)(14)(i)), with Docket Item 38-2 at 4 (arguing that "two patient matters cannot reasonably be considered a 'pattern or practice' of overall prescribing activity" under 42 C.F.R. § 424.535(a)(14)); 17 (contending that 42 C.F.R. § 424.535(a)(14) "expressly requires that . . . CMS must consider at least eight [] specific factors" before revocation but arguing that the "July 23 [letter] reflect[ed] consideration of merely two of the factors").

While Dr. Pawlowski couches some of his claims in terms of general attacks on the statutory or regulatory regime, "[a] party's characterization of its challenge to the Secretary's termination of a provider agreement as a purely legal or statutory question[] . . . is not sufficient by itself to constitute an 'entirely collateral' claim." *Cathedral Rock*, 223 F.3d at 363. And at their core, Dr. Pawlowski's challenges to the regulatory regime are challenges to the grounds behind the revocation and preclusion decisions. Indeed, the relief that Dr. Pawlowski seeks suggests as much. See, e.g., Docket Item 27 at ¶¶ 67 ("Dr. Pawlowski is entitled to a judgment declaring that [the government's

determinations] are invalid ab initio"); 70 (seeking "permanent . . . injunctive relief enjoining [the government] from effectuating any revocation of Dr. Pawlowski's Medicare enrollment"); 80 (requesting that "this Court [] vacate the determinations to terminate Dr. Pawlowski's Medicare enrollment and agreement and to include him on the CMS [p]reclusion [l]ist"). And without exhaustion of the administrative process, this Court cannot invalidate or enjoin the administrative decision at this stage of the process.⁷ See *Fox Ins. Co. v. Sebelius*, 381 F. App'x 93, 96 (2d Cir. 2010) (summary order) (noting that "the relief [the plaintiff] sought belies its assertion that it only seeks to challenge the interpretation and implementation of CMS regulations" where the plaintiff sought, among other relief, an order "requiring CMS to withdraw its letter purporting to terminate [the plaintiff] as a Medicare Part D Plan Sponsor" (alterations omitted)).

But not all of Dr. Pawlowski's claims are inextricably intertwined with the administrative decision itself. Dr. Pawlowski also alleges that the government violated his due process rights by failing to provide him notice and an opportunity to be heard before sending the July 23 letter. See Docket Item 27 at ¶¶ 29-35. That claim would require this Court to evaluate only the adequacy of the notice and hearing afforded to Dr. Pawlowski and would not contemplate a wholesale reversal of the revocation and preclusion decisions. Stated another way, relief on that claim would give Dr. Pawlowski

⁷ Dr. Pawlowski acknowledges that his demands for vacatur or reversal may hew too closely to a substantive challenge to the revocation and preclusion decisions themselves. See Docket Item 37 at 19. But even if his complaint did not explicitly seek that relief, the bulk of Dr. Pawlowski's claims are "fundamentally aimed at upending [a] particular administrative outcome"—namely, the decision to revoke his enrollment, bar him from re-enrolling, and place him on the preclusion list. See *Arriva Med.*, 239 F. Supp. 3d at 279.

only an opportunity to challenge the administrative decision before any deprivation went into effect.

The government concedes that such a procedural due process claim “could be collateral.” Docket Item 43 at 6. And other courts have considered such a constitutional due process claim to be collateral to any claims that target the administrative decision itself. See, e.g., *Arriva Med.*, 239 F. Supp. 3d at 279 (“Since *Eldridge*, due-process ‘claims to a predeprivation hearing as a matter of constitutional right’ have fit under this narrow exemption, as they are not fundamentally aimed at upending any particular administrative outcomes.” (alterations omitted) (quoting *Eldridge*, 424 U.S. at 331)); see also *Ram v. Heckler*, 792 F.2d 444, 446 (4th Cir. 1986); *Robie*, 2017 WL 3097529, at *5.⁸

This Court agrees: Dr. Pawlowski’s claim that the defendants “deprived [him] of due process by failing to afford him any opportunity to be heard prior to the revocation determination” and “by not providing him an opportunity to rebut [the] findings that influenced the revocation determination” are wholly collateral to any claim for continued

⁸ The cases Dr. Pawlowski cites do not suggest that his other claims are collateral. For example, in *Niskayuna Operating Co., LLC v. Sebelius*, 2010 WL 4248852 (N.D.N.Y. Oct. 26, 2010), the court excused exhaustion for the plaintiff’s challenges to, among other things, the Secretary’s statutory authority to terminate its provider agreement. See *id.* at *4. But for all the reasons stated above, this Court respectfully disagrees that it has jurisdiction to entertain a claim that is so inextricably intertwined with a claim for continued participation. See *Cathedral Rock*, 223 F.3d at 363. And in *St. Francis Hospital v. Sebelius*, 874 F. Supp. 2d 127 (E.D.N.Y. 2012), the court determined that a claim challenging “the purported lack of appellate remedies available to address” an administrative decision was collateral. See *id.* at 133-34. But unlike that case, Dr. Pawlowski has placed “the merits of the []determination below,” *id.* at 133, at issue in his amended complaint, see, e.g., Docket Item 27 at ¶¶ 36-49. Likewise, in *Aurora Chicago Lakeshore Hospital v. Azar*, 356 F. Supp. 3d 749 (N.D. Ill. 2018), the plaintiff did not substantively challenge the “propriety of [the] termination.” See *id.* at 758.

participation in the Medicare program. Docket Item 27 at 11-12 (capitalization removed). That claim targets only the sufficiency of the process afforded to Dr. Pawlowski prior to any deprivation, not the substance or the validity of the revocation determination itself. For that reason, collateralality favors waiving exhaustion for that claim.

2. Whether Exhaustion Would Be Futile

Dr. Pawlowski also argues that administrative exhaustion should be excused because exhaustion would be futile. Docket Item 37 at 19-21. More specifically, Dr. Pawlowski asserts that there is no reason to channel his claims through the administrative process because CMS is “categorically prohibited from resolving th[e] issues” that are raised in his amended complaint. *See id.* at 19. And Dr. Pawlowski argues that exhaustion is futile because his challenges are to “regulations promulgated and consistently enforced by the agency, [] which the agency has either no power, or no inclination, to correct.” *Id.* at 20 (quoting *Abbey*, 978 F.2d at 45).

To be sure, a number of Dr. Pawlowski’s allegations apparently target the validity of the statutes or regulations themselves. *See, e.g.*, Docket Item 27 at ¶¶ 36-64. But those same allegations also challenge the application of the statutes and regulations to *him*. *See, e.g.*, *id.* at ¶¶ 41 (alleging that “the regulations are unconstitutionally vague as applied to Dr. Pawlowski[] and their nonsensical application to this situation has deprived him of due process”); 47 (arguing that “the revocation determination was made in the absence of any meaningful standards and/or on the basis of standards that are void for their vagueness”); 61 (contending that the regulations governing the re-enrollment bar and preclusion list are “impermissibly vague[] and [the] [d]efendants’

application of them to Dr. Pawlowski violated due process" (emphasis added)).

Allowing Dr. Pawlowski's claims to continue through the administrative process would prevent "possibly premature interference" by this Court; "assure [that] the agency [has] a] greater opportunity to apply, interpret, or revise policies, regulations, or statutes"; and still permit this Court to later review the actual basis for any ultimate revocation. *III.*

Council, 529 U.S. at 13. Moreover, to the extent that Dr. Pawlowski asks this Court to "vacat[e] the determination[] to revoke [his] Medicare enrollment, terminate his Medicare agreement, and include him on the [] [p]reclusion [l]ist," Docket Item 27 at 24, he still may obtain that relief through the administrative process. See *Skubel v. Fuoroli*, 113 F.3d 330, 334-35 (2d Cir. 1997) (collecting cases finding exhaustion futile where the agency has "taken a firm stand" or "where there is no realistic possibility that the agency will change its position" (internal quotation marks omitted)).

Finding that exhaustion "would be futile is merely another way of stating that the policies underlying the exhaustion requirement do not apply in a given case." *Abbey*, 978 F.2d at 45. Dr. Pawlowski already has raised a number of the challenges he presses here before the agency, and he presumably will continue to do so throughout the administrative process. On that basis, and for the reasons noted above, this Court finds that futility does not excuse the exhaustion requirement for any of Dr. Pawlowski's non-collateral claims.⁹

⁹ This Court does conclude, however, that futility would favor exercising jurisdiction over Dr. Pawlowski's claim that he did not receive an adequate notice and opportunity to be heard prior to deprivation. By the time Dr. Pawlowski completes administrative review, the opportunity for a pre-deprivation hearing will have come and gone—no matter what the outcome of the administrative process is.

3. Whether Dr. Pawlowski Would Suffer Irreparable Harm

Finally, Dr. Pawlowski contends that requiring exhaustion would subject him to irreparable harm. See *Abbey*, 978 F.2d at 44. He alleges that revocation of his Medicare enrollment—even if it subsequently is reinstated after his administrative appeal—would “render him unable to continue care for his patients.” Docket Item 27 at ¶ 6. And he alleges that revocation would “destroy his practice,” forcing his patients “to find alternate care” and “jeopardiz[ing] the[ir] well-being” in the process.¹⁰ *Id.*

The Court finds that this factor does not itself excuse exhaustion. As an initial matter, Dr. Pawlowski may continue to see Medicare beneficiaries while his administrative appeal is pending and ultimately can recover any unpaid reimbursement if his appeal proves successful. See 42 C.F.R. § 424.545(a)(2). And similar allegations that a plaintiff “w[ould] go out of business before the appeals process is completed” have been deemed insufficient to deem exhaustion waived based on irreparable harm. See *Integrity Soc. Work Servs., LCSW, LLC. v. Azar*, 2021 WL 4502620, at *12

¹⁰ Dr. Pawlowski argues that the claims in his amended complaint are “constitutional deprivations [that] constitute[] per se irreparable harm.” Docket Item 37 at 21. But as noted above, a party cannot “avoid the Medicare Act’s administrative procedures for review[] . . . simply by making purely legal constitutional or statutory arguments.” *Cathedral Rock*, 223 F.3d at 363. And for all the reasons above, this Court concludes that Dr. Pawlowski’s claims are the sort of claims that are subject to administrative exhaustion.

In his affidavit, Dr. Pawlowski also contends that revocation would “permanently tarnish [his] reputation in the medical community” because he would “need to disclose the revocation on future credentialing and insurance network applications.” Docket Item 4 at ¶ 21; see also Docket Item 27 at ¶ 21. But because Dr. Pawlowski still may continue to challenge the revocation and preclusion decisions through the administrative process and ultimately in court, at this stage this Court cannot say whether possible harm to his reputation would indeed be “permanent[.]” Docket Item 4 at ¶ 21.

(E.D.N.Y. Oct. 1, 2021) (finding no irreparable harm where the plaintiff alleged financial harm that “pose[d] an existential threat to [its] business”); *cf. Thorbus v. Bowen*, 848 F.2d 901, 904 n.7 (8th Cir. 1988) (no irreparable harm warranting injunctive relief where suspension of reimbursement would affect “60% of [the plaintiff’s] gross income”). Nor is it clear that the sort of third-party harm that Dr. Pawlowski invokes could show that *he* would suffer irreparable injury absent waiver of exhaustion. See *Cathedral Rock*, 223 F.3d at 364 (rejecting argument that nursing facility can “rely solely on the irreparable harm to its patients in [the irreparable harm] analysis”) (citing *O’Bannon v. Town Court Nursing Ctr.*, 447 U.S. 773, 787-90 (1980)).

On balance, therefore, this Court does not find that irreparable harm justifies excusing exhaustion here.¹¹

4. Conclusion

Precisely how to weigh each of the above factors is unclear. The Second Circuit has suggested that the “courts should be flexible in determining whether exhaustion should be excused” and should be “guided by the policies underlying the exhaustion requirement.” *Pavano*, 95 F.3d at 151 (quoting *Bowen v. City of New York*, 476 U.S. 467, 484 (1986)). For the reasons stated above, this Court concludes that futility and

¹¹ In addition to arguing that Dr. Pawlowski has not made a sufficient showing of irreparable harm, the government also argues that this Court lacks jurisdiction because Dr. Pawlowski’s constitutional claim itself is not “colorable.” See Docket Item 31-1 at 18-19. Other circuits have refused to excuse exhaustion after concluding that claims to additional process in the Medicare context are not colorable legal claims. See, e.g., *Cathedral Rock*, 223 F.3d at 366; *Anderson v. Sullivan*, 959 F.2d 690, 693 (8th Cir. 1992). In the absence of any guidance from the Second Circuit foreclosing the sort of due process claim that Dr. Pawlowski raises here, this Court concludes that his collateral constitutional claim is at least colorable. But those decisions foreshadow the ultimate deficiencies in the due process claim that Dr. Pawlowski presses here.

collaterality favor deciding only Dr. Pawlowski's procedural due process claim now. But the remainder of Dr. Pawlowski's claims, which challenge the government's decision to revoke his Medicare enrollment and place him on the preclusion list, are "inextricably intertwined" with his claim for continued participation in the program itself. For that reason, and because exhausting those claims would not be futile, this Court exercises jurisdiction only over Dr. Pawlowski's claim that he was deprived of adequate notice and an opportunity to be heard prior to deprivation.

C. Alternative Bases for Jurisdiction

In the alternative, Dr. Pawlowski contends that this Court has mandamus jurisdiction or jurisdiction under the APA. See Docket Item 37 at 24-25.

But mandamus is not a basis for jurisdiction here. Regardless of whether the Secretary owed Dr. Pawlowski some non-discretionary duty before terminating his enrollment, barring him from re-enrolling, and placing him on the preclusion list, this Court already has determined that Dr. Pawlowski's claims—with the exception of the procedural due process claim over which this Court does have jurisdiction—must be exhausted through the administrative process. As a result, mandamus relief is inappropriate here. See *Abbey*, 978 F.2d at 47 ("[O]ne of the requisites for obtaining a writ of mandamus is that the plaintiff have exhausted all other adequate remedies.").

Nor does this Court have jurisdiction under the APA. For all the reasons stated above, this Court lacks federal question jurisdiction under 28 U.S.C. § 1331 over Dr. Pawlowski's APA claim because of the channeling provisions of the Medicare Act.¹²

¹² To the extent that Dr. Pawlowski argues that section 706 of the APA itself supplies an independent source of jurisdiction, that argument does not get out of the starting gate. See *Your Home Visiting Nurse Servs., Inc. v. Shalala*, 525 U.S. 449, 457-

II. PROCEDURAL DUE PROCESS

Because Dr. Pawlowski is left with only a procedural due process claim that he lacked adequate notice and an opportunity to be heard prior to deprivation, the Court next considers whether that claim is viable. “A procedural due process claim is composed of two elements: (1) the existence of a property or liberty interest that was deprived and (2) deprivation of that interest without due process.” *Bryant v. N.Y. State Educ. Dep’t*, 692 F.3d 202, 218 (2d Cir. 2012).

A. Protected Interest

The government first contends that Dr. Pawlowski’s procedural due process claim stumbles at the first hurdle—that is, that he has no protected interest in continued enrollment in the Medicare program. See Docket Item 31-1 at 27-29. At least five circuits have held the same. See *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019); *Parrino v. Price*, 869 F.3d 392, 397-98 (6th Cir. 2017) (collecting cases). Although the Fourth Circuit concluded otherwise, see *Ram*, 792 F.2d at 447, other circuits have “explicitly rejected that conclusion,” see *Shah*, 920 F.3d at 997 n.30. The Second Circuit apparently has not squarely held one way or the other, but it previously suggested in dicta that “[h]ealth care providers have a constitutionally protected property interest in continued participation in the Medicare . . . program[].”¹³ *Patchogue*

58 (1999) (“[W]e have long held that this provision is not an independent grant of subject-matter jurisdiction.”).

¹³ Dr. Pawlowski does not argue that he has a protected liberty interest in continued Medicare enrollment in his response. See Docket Item 37 at 27-28.

Nursing Ctr. v. Bowen, 797 F.2d 1137, 1144-45 (2d Cir. 1986); *see Plaza Health Labs., Inc. v. Perales*, 878 F.2d 577, 582 (2d Cir. 1989) (recognizing above as dicta).

In any event, this Court need not resolve that dispute today. Because Dr. Pawlowski now has received adequate process, he has failed to state a claim that his procedural due process rights were violated.

B. *Eldridge* Balancing

A due process claim under *Eldridge* “generally requires consideration of three distinct factors”: (1) “the private interest that will be affected”; (2) “the risk of an erroneous deprivation . . . through the procedures used[] and the probable value[] . . . of additional or substitute procedural safeguards”; and (3) “the [g]overnment’s interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.” *Eldridge*, 424 U.S. at 335.

A brief description of the revocation, reconsideration, and appeals process in this matter informs this Court’s evaluation under *Eldridge*. After notice is sent to a supplier, revocation of enrollment generally becomes effective after thirty days. 42 C.F.R. § 424.535(g). The supplier can challenge the revocation decision by first submitting a request for reconsideration after receiving initial notice.¹⁴ *See id.* §§ 498.5(l)(1), 498.22. As part of that request, the supplier may submit any evidence relevant to the revocation decision. *See id.* § 405.803(c).

If the reconsideration decision is unfavorable, the supplier may then pursue an oral hearing before an Administrative Law Judge (“ALJ”). *See* 42 C.F.R. §§ 498.5(l)(2),

¹⁴ Appeal of an “individual’s or entity’s inclusion on the preclusion list” is “considered jointly” under the same regulations. 42 C.F.R. § 422.222(a)(2)(ii)(B).

498.40. Those hearings include a host of procedural safeguards, including “the ability to subpoena and call witnesses,” and to “present oral summation and [] file briefs or other written statements of proposed findings of fact and conclusions of law.” See *Arriva Med.*, 239 F. Supp. 3d at 287 (citing 42 C.F.R. §§ 498.58, 498.62, 498.63).

If the ALJ reaffirms the revocation, the supplier then can pursue a final level of administrative review before the HHS Departmental Appeals Board. See 42 C.F.R. §§ 498.5(l)(3), 498.80. The parties again may “file briefs or other written statements as to fact and law,” and may “present evidence or oral arguments.” *Id.* § 498.85.

After all that, a supplier whose initial revocation decision has been reaffirmed after three levels of review may pursue an action in federal court. See 42 U.S.C. § 1395cc(j)(8). As noted above, judicial review is conducted in accordance with section 405(g). *Id.*

With all that in mind, the Court addresses whether more process is due under the *Eldridge* factors. None favor Dr. Pawlowski here.

1. The Private Interest

First, other courts have determined that a provider’s or supplier’s interest in continued participation in Medicare is not particularly weighty under *Eldridge*. That is because providers and suppliers are “not the intended beneficiar[ies] of the Medicare program.”¹⁵ See *Arriva Med.*, 239 F. Supp. 3d at 289 (quoting *Cathedral Rock*, 223

¹⁵ *Robie*, the principal case on which Dr. Pawlowski relies to argue otherwise, acknowledged that other circuits have generally held that “physicians are not the intended beneficiaries of the Medicare program” before simply concluding that the “private interest factor still weighs in favor” of the plaintiff. 2017 WL 3188572, at *5. And in *Aurora Chicago Lakeshore Hospital*, the second case that Dr. Pawlowski invokes, the court evaluated the strength of the private interest at stake in concluding

F.3d at 364-65); *see also Native Angels Home Health, Inc. v. Burwell*, 123 F. Supp. 3d 775, 778 (E.D.N.C. 2015) (same); *Blossom South*, 987 F. Supp. 2d at 298 (same). “Although termination of its agreement may have a severe economic impact on the provider” or supplier, a provider’s or supplier’s “financial need to be subsidized for the care of its Medicare patients is only incidental to the purpose and design of the Medicare program.” *Cathedral Rock*, 223 F.3d at 365 (alterations omitted). And that is true even where, as here, the plaintiff challenging termination represents that revocation “would likely be tantamount to shutting down the [practice]” altogether. *See Blossom South*, 987 F. Supp. 2d at 298 (noting that “plaintiff has submitted evidence that 98% of its residents and gross revenue come from participation in the Medicare and Medicaid programs” but nevertheless concluding that “the private interest at stake is not particularly strong”).

2. The Risk of Erroneous Deprivation and the Value of Additional Safeguards

Regardless of the strength of the private interest at stake, however, Dr. Pawlowski’s claim founders on the second *Eldridge* factor. Other courts generally have rejected claims that additional pre-deprivation process is necessary for Medicare providers or suppliers. *See, e.g., Arriva Med.*, 239 F. Supp. 3d at 287 (collecting “appellate decisions that have denied the need for courts to supplement the Medicare scheme with additional pre-deprivation procedures”); *Native Angels Home Health*, 123 F. Supp. 3d at 777 (“[D]ue process does not require a pre-deprivation hearing where a

that exhaustion was excused, not in connection with the merits of the plaintiff’s due process claim. *See Aurora Chicago Lakeshore Hosp.*, 356 F. Supp. 3d at 759.

Medicare provider is stripped of its billing privileges."); *Blossom South*, 987 F. Supp. 2d at 298 ("Federal courts have held that a nursing home or similar facility has no constitutional right to a hearing prior to the termination of its Medicare . . . provider agreement.").

What is more, Dr. Pawlowski has, in fact, been given notice and an opportunity to challenge his revocation. After Dr. Pawlowski filed his initial complaint in this Court, the government agreed to stay the effective date of revocation and preclusion until twenty-one days after his request for reconsideration was decided. See Docket Item 15. Dr. Pawlowski then submitted a reconsideration request that exceeded 300 pages; he attached fifteen exhibits, including "supplemental medical records" for patients referenced in the July 23 letter as well as additional affidavits from physicians and a medical billing expert. See Docket Item 38-1 at ¶ 4; Docket Item 38-2.

All of that occurred before the revocation and preclusion decisions became effective—that is, before any deprivation actually occurred. So Dr. Pawlowski's challenges to the process that took place before the July 23 letter are beside the point: He now has received notice and an "opportunity to present reasons[] . . . why [the] proposed action should not be taken" prior to any actual deprivation. *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 546 (1985). Because Dr. Pawlowski has had a "pre-deprivation opportunity to respond" and a "meaningful pre-deprivation opportunity to be heard"—the same "due process require[ments]" that he alleges apply before any ultimate deprivation, see Docket Item 27 at ¶¶ 29-35—this Court sees no basis to order additional process here.

Dr. Pawlowski argues that the risk of erroneous deprivation is nevertheless high because the individuals who initially decided to revoke his enrollment may lack relevant expertise in the substantive basis for the revocation decision; because the “background or qualifications” of the individual deciding his request for reconsideration are unknown; and because Dr. Pawlowski’s “situation” may not be sufficiently serious to warrant revocation under 42 C.F.R. § 424.535(a)(14), which Dr. Pawlowski claims is used to revoke the enrollment of only about fifteen providers each year.¹⁶ See Docket Item 37 at 36-37. But those contentions invite this Court to investigate whether the substance of the revocation decision is correct. For all the reasons addressed above, this Court does not have jurisdiction to second-guess the substantive validity of that decision—at least not at this point in the process.

3. The Government’s Interest

Finally, the government’s interest in maintaining programmatic compliance is strong. Courts have recognized the government’s “strong interest in minimizing the expenses of administering the Medicare program.” *Cathedral Rock*, 223 F.3d at 365; see also *Blossom South*, 987 F. Supp. 2d at 298 (noting that “the government has a strong interest in ‘expeditious provider termination procedures’” (quoting *Northlake Cnty. Hosp. v. United States*, 654 F.2d 1234, 1242 (7th Cir. 1981))). Moreover, the government at this point has determined twice—first in its July 23 letter and again in its denial of Dr. Pawlowski’s reconsideration request—that Dr. Pawlowski has engaged in a “pattern or practice” of prescribing drugs that “is abusive or represents a threat to the

¹⁶ All those contentions are raised in Dr. Pawlowski’s response, not in his amended complaint. Compare Docket Item 37 at 36-37, with Docket Item 27.

health and safety of Medicare beneficiaries.” See 42 C.F.R. § 424.535(a)(14)(i); see also Docket Item 27-1; Docket Item 44. Considering the fact that Dr. Pawlowski has been given an opportunity to challenge that determination, this Court sees little need to upset the government’s interest in ensuring effective compliance by providing Dr. Pawlowski with additional process here.¹⁷

4. Conclusion

In sum, none of the relevant *Eldridge* considerations favor Dr. Pawlowski here. His private interests have not been recognized as particularly strong and the government’s interest in programmatic compliance is weighty. And, most significantly, his due process claim hinges on the alleged inadequacy of his opportunity to respond prior to any deprivation, but he now has been given that opportunity—before any deprivation became effective. For all those reasons, Dr. Pawlowski’s procedural due process claim lacks merit. See *Blossom South*, 987 F. Supp. 2d at 299.

CONCLUSION

This Court lacks jurisdiction over the bulk of Dr. Pawlowski’s claims. And Dr. Pawlowski has failed to adequately allege a due process violation for the claim that this Court does have jurisdiction to hear now. For the reasons stated above, the

¹⁷ Dr. Pawlowski contends that the government may actually have an interest in “additional pre-deprivation process” because that process would “[s]creen[] out cases that do not warrant sanction at an early stage.” Docket Item 37 at 39. But the government’s interest is in preserving its existing regulatory scheme, not adopting whatever scheme Dr. Pawlowski would prefer.

government's motion to dismiss, Docket Item 31, is GRANTED. Dr. Pawlowski's motion for a preliminary injunction, Docket Item 3, accordingly is DENIED as moot.

Because Dr. Pawlowski already has had the opportunity to amend his complaint, leave to amend is denied. The Clerk of the Court shall close the case.

SO ORDERED.

Dated: March 2, 2022
Buffalo, New York

/s/ *Lawrence J. Vilardo*
LAWRENCE J. VILARDO
UNITED STATES DISTRICT JUDGE